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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,554	02/09/2004	Meng Yang	312762004400	6701

25225 7590 05/10/2011

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EXAMINER	
WEHBE, ANNE MARIE SABRINA	
ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
05/10/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

EOfficeSD@mofo.com
PatentDocket@mofo.com
Drcaldwell@mofo.com

Office Action Summary	Application No.	Applicant(s)	
	10/775,554	YANG ET AL.	
	Examiner	Art Unit	
	ANNE MARIE S. WEHBE	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 22-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/27/11 has been entered. Applicant's amendment filed with the RCE added new claims 22-24. Claims 1-3 and 22-24 are therefore pending and under examination. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in a previous office action.

Claim Rejections - 35 USC § 103

The rejection of claims 1-3 under 35 U.S.C. 103(a) as being unpatentable over Okabe et al. (1997) FEBS Lett., Vol. 467, 313-319, in view of WO 02/28188 A1 (4/1/02), hereafter referred to as Kern, and Yang et al. (2002) PNAS, Vol. 99(6), 3824-3829, is maintained over amended and new claims 1-3 and 22-24. Applicant's amendments, arguments, and the Declaration under 37 CFR 1.132 by Dr. Hoffman have been fully considered but have not been found persuasive in overcoming the rejection for reasons of record as discussed in detail below.

The applicant argues that the claims as amended make clear the distinction between the claimed rodent and the disclosures of the cited prior art. The applicant further argues that the

Declaration of Robert M. Hoffman states that the inventors discovered that whereas the heterozygous transgenic fluorescent immunocompromised mice can be used as a tumor model system, the homozygous transgenic fluorescent immunocompromised mice were not sufficiently sturdy to server as a tumor model system. According to applicants, while Okabe et al. does in fact teach a heterozygous transgenic fluorescent mouse, Okabe et al. does not teach that the mouse is immunocompromised. Further, the applicant argues that while Kern et al. teaches that the fluorescent trait can be homozygous or heterozygous and can be crossed with an immunodeficient mouse, Kern et al. does not teach the necessity of the heterozygous genotype. The applicant therefore concludes that Kern et al. teaches away from instant invention because Kern et al. failed to appreciate that heterozygosity of the fluorescent transgene in an immunocompromised rodent is required in order for the rodent to be able to tolerate a foreign tumor.

In response, it is first noted that the claims as amended now recite an immunocompromised transgenic rodent heterozygous for a fluorescent transgene. However, applicant's response acknowledges that both Okabe et al. and Kern et al. teach such a heterozygous fluorescent transgenic rodent, and in particular a mouse, and that Kern et al. further teaches to cross the heterozygous mouse with a immunocompromised mammal, in particular a nu/nu mouse. Applicant's argument against obviousness is that Kern et al. teaches away from the instant invention by failing to appreciate that the heterozygous fluorescent immunocompromised rodent would make a better recipient for a foreign tumor than a homozygous fluorescent immunocompromised rodent. However, as acknowledged by applicant, Kern et al. clearly provides teachings to use a heterozygous transgenic fluorescent mouse crossed with an

immunocompromised mouse as a recipient for foreign tissue (Kern et al., see especially pages 9-11). Thus, it is strongly disagreed that Kern et al. teaches away from the heterozygous transgenic fluorescent immunocompromised mouse since Kern et al. clearly teaches to make an use this particular embodiment. That Kern et al. also teaches to make an use the homozygous transgenic fluorescent mouse is not a "teaching away", since nothing in Kern et al. discourages or in any way dissuades the skilled artisan from making and using the heterozygous transgenic mouse. Thus, applicant's arguments that Kern et al. teaches away from the instant invention is not persuasive.

Regarding the Hoffman Declaration, the Declaration states that immunocompromised mice homozygous for a fluorescent transgene were unable to tolerate implantation of foreign tumors, and that prior to applicant's work, it was not understood that heterozygosity of the fluorescence gene in an immunocompromised background was a requirement for use of this system as a tumor model. While not explicitly argued by applicant, it would appear that the Declaration of Dr. Hoffman seeks to establish that the claimed heterozygous mice exhibit unexpected properties. In response, the claims as written are product claims (claims 1-3) and product by process claims (claims 22-24). In regards to the product by process claims (claims 22-24), it is again reiterated that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Second, it is noted that

the claims as written contain no limitations regarding the stability of the rodent containing the tumor or its ability to act a tumor model. Further, since Kern et al. clearly teaches that the heterozygous transgenic fluorescent mouse can be bred with an immunodeficient strain, such as the nu/nu mouse, to produce a recipient mouse for donor tissue transplantation, and Okabe et al. teaches to transplant non-green tumors into green mice, it is maintained that the skilled artisan would have reasonably expected that a heterozygous transgenic fluorescent immuno-compromised rodent would be capable of being transplanted with tumor tissue. The unexpected result disclosed in the Declaration in fact pertains to the homozygous transgenic fluorescent immunocompromised mouse, which the applicant determined could not tolerate tumor transplantation, and not to the claimed heterozygous strain. However, the properties of the homozygous fluorescent mouse are not probative as to whether the skilled artisan at the time of filing would have been motivated to make the heterozygous strain as claimed, and there is no evidence or argument that the ability of the heterozygous transgenic immunocompromised mice to accept tumors was in any way unexpected. Therefore, while the Hoffman Declaration has been fully and respectfully considered, it has not been found persuasive in overcoming the rejection of record.

The rejection of claims 1-3 under 35 U.S.C. 103(a) as being unpatentable over Okabe et al. (1997) FEBS Lett., Vol. 467, 313-319, in view of WO 02/28188 A1 (4/1/02), hereafter referred to as Kern, and Verkhusha et al. (2001) J. Biol. Chem., Vol. 276(32), 29621-29624, is maintained over amended and new claims 1-3 and 22-24. Applicant's amendments, arguments, and the Declaration under 37 CFR 1.132 by Dr. Hoffman have been fully considered but have

not been found persuasive in overcoming the rejection for reasons of record as discussed in detail below.

The applicant argues that similar concepts argued in the response to the rejection of the claims over Okabe et al., Kern et al. and Yang et al. apply to the instant rejection. The response to applicant's arguments and the evidence of the Hoffman Declaration have been set forth in detail above. As discussed in detail above, applicant's amendments, arguments, and the Declaration under 37 CFR 1.132 by Dr. Hoffman have not been found persuasive. Therefore, for the reasons set forth above, the rejection of record stands.

No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Joseph Woitach, can be reached at (571) 272-0739. For all official communications, the technology center fax number is (571) 273-8300. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197.

Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

/Anne Marie S. Wehbé/
Primary Examiner, A.U. 1633